

Applicants: Soderlund *et al.*
Serial No.: 08/465,322
Filed: June 5, 1995
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Claims 56, 57, 59 and 62 have been amended to recite "detection primer" before the sequences. Support for this amendment can be found throughout the specification, and for example, at page 15, line 1-22.

New claims 70-96 have been added. These claims find support throughout the specification. Claim 76 and 87 for example, finds support in the specification at page 7, lines 7-12.

Claims 70-74, 81-82, and 91-92 find support throughout the specification, and for example, at page 16, lines 13-20.

Claims 83 and 93 find support in the specification at, for example, page 17, lines 12-19.

Claims 85 and 95 find support in the specification, for example, at page 19, lines 26-30.

Claim 77 finds support in the specification at, for example, page 10, lines 10-13.

Claims 79 and 89 find support in the specification, for example, at page 15 lines 10-12.

No new matter has been added.

Claims 51-53, 56, 57, 59, 62 to 67 and 70-96 are now pending.

Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 51-68 under 35 U.S.C. § 112, first paragraph. According to the Examiner the claims contain subject matter not described in the specification in such a way as to reasonably convey that the applicants were in possession of the claimed

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invention at the time of filing. Specifically, the Examiner states, with regard to claim 68, that the specification does not describe any methods in which a double-stranded hybrid is formed.

Applicants disagree with this conclusion because the methods described in the specification comprise a hybridization step where target nucleic acid polymers hybridize with detection step primers. Applicants, to expedite prosecution, have canceled claim 68 and reserve the right to prosecute this claim in the future. Accordingly, Applicants respectfully submit that this rejection has been obviated.

For claims 51-68, the examiner states that there is no basis in the specification for kits comprising the target nucleic acid. Claim 51 has been amended so that the target nucleic acid is not included in the kit. Applicants respectfully submit that this rejection has been obviated.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 54-62, 68 and 69 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to the Examiner claims 54-62 are indefinite because is unclear what is meant by a kit having a sequence. In accordance with the Examiner's suggestion, claims 56, 57, 59, and 62 have been amended to recite "detection primer" before sequence.

Claims 54, 55, 58, 60, 61, 69, and 69 have been canceled. Applicants reserve the right to prosecute the canceled claims at a later date.

Accordingly, it is respectfully submitted that this rejection has been obviated.

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First Rejection Under 35 U.S.C. § 102(e)

Claim 69 has been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,310,893 to Erlich *et al.* (hereinafter "Erlich").

Applicants have canceled claim 69 and reserve the right to prosecute this claim at a later date. Accordingly, it is respectfully submitted that this rejection has been obviated.

Second Rejection Under 35 U.S.C. § 102(e)

Claim 69 has been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,846,710 to Bajaj (hereinafter "Bajaj").

Applicants have canceled claim 69 and reserve the right to prosecute this claim at a later date. Accordingly, it is respectfully submitted that this rejection has been obviated.

First Rejection Under 35 U.S.C. § 103(a)

Claims 51-53 and 63-69 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Erlich in view of U.S. Patent No. 4,683,202 to Mullis.

Claim 51 has been amended to recite "at least one deoxynucleotide and at least one chain terminating nucleotide analogue." It is respectfully submitted that neither Erlich nor Mullis teach or suggest the use of reagents that have both deoxynucleotides and terminating nucleotides. The disclosure of both of these patents describes amplification type primer extension which does not encompass chain termination or the presence of chain terminators. Claims 52, 53 and 63-69 are all dependent from claim 51, which is believed to be patentable over Erlich in combination with Mullis. These claims are believed to be patentable, because of, among other reasons, their dependency from claim 51. Accordingly, it is respectfully submitted that this rejection has been overcome.

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Second Rejection Under 35 U.S.C. § 103(a)

Claims 51-53, 64 and 68 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bajaj.

Claim 51 has been amended to recite "at least one deoxynucleotide and at least one chain terminating nucleotide analogue." Bajaj does not teach or suggest the use of a mixture comprising both deoxynucleotides and chain terminators in a reagent kit for detecting the presence of a specific nucleotide at a predetermined position. In fact, Bajaj discloses only one type of nucleotide being used in their method at any one time. Only one of the four nucleotides is included in each reaction mixture. See Bajaj at column 3, lines 25-35. The use of terminators is not disclosed in Bajaj. The methods of the application have been distinguished from Bajaj in an interference proceedings for parent application 08/162,375, now U.S. patent No. 6,013,141. The reagent claims now pending are consonant with the conclusion of the interference proceeding. It is submitted that claims 52 and 53 are patentable because, among other reasons, they depend from claim 51. Claims 64 and 68 have been canceled. It is respectfully submitted that this rejection has been overcome.

Third Rejection Under 35 U.S.C. § 103(a)

Claims 52, 63, and 65-67 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bajaj in view of Erlich.

Erlich is cited for the disclosure regarding immobilizing primers to supports. Claims 52, 63 and 67 have been rejected over the combination of Bajaj and Erlich, with Erlich adding the immobilization of primers. For the reasons discussed above, Applicants believe that claim 51 is patentable over Bajaj. Therefore, it is respectfully submitted that claims 52, 63 and 67 are all patentable over the combination of Bajaj and Erlich because, among other reasons, of their dependency from claim 51. Claim 65 and 66 have been canceled. Applicants respectfully

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submit that this rejection has been overcome.

Fourth Rejection Under 35 U.S.C. § 103(a)

Claims 54-57 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bajaj in view of Emi *et al.*, *Genomics* 3:373-379 (1988).

Applicants believe for the reasons stated above that amended claim 51 is patentable over Bajaj. Therefore, it is respectfully submitted that claims 56 and 57 are patentable because of their dependency from claim 51. Claims 54 and 55 have been canceled. It is therefore respectfully submitted that this rejection has been overcome.

Fifth Rejection Under 35 U.S.C. § 103 (a)

Claims 58-59 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bajaj in view of Saiki *et al.*, *Nature* 324:163-166 (1986).

Applicants believe for the reasons stated above that amended claim 51 is patentable over Bajaj. Therefore, it is respectfully submitted that claim 59 is patentable because of its dependency from claim 51. Claim 58 has been canceled. It is therefore respectfully submitted that this rejection has been overcome.

Sixth Rejection Under 35 U.S.C. § 103(a)

Claims 60-62 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bajaj in view of Farr *et al.*

Applicants believe for the reasons stated above that amended claim 51 is patentable over Bajaj. Therefore, it is respectfully submitted that claim 62 is patentable because of its dependency from claim 51. Claims 60 and 61 have been canceled. It is therefore respectfully

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submitted that this rejection has been overcome.

Conclusion:

In view of the foregoing amendments to the claims, and the remarks set forth above, reconsideration and allowance are respectfully solicited.

If any additional fees are due or any overpayment has been made, please charge our Deposit Account No. 11-0171 or credit our Deposit account for such sum. A duplicate copy of this sheet is enclosed for that purpose.

Respectfully submitted,

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